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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,320	11/23/2001	Francine Goulet	216483US6	2528

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EXAMINER

LANDREM, KAMRIN R

ART UNIT PAPER NUMBER

3738

DATE MAILED: 12/22/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,320

Applicant(s)

GOULET ET AL.

Examiner

Kamrin R. Landrem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 25-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 45-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein (USPN 5,613,982) in view of Campbell et al (USPN 5,067,962).

Goldstein discloses an implant for connective tissue substitution that comprises a matrix layer that is colonized by a fibroblast and a pharmaceutically effective amount of a biologically active molecule. Goldstein discloses all of the claimed elements except for the particulars pertaining to the specific implant structure. Campbell et al teaches a bioprosthetic ligament for replacing a damaged ligament comprising a pair of bone anchors joined together at their proximal ends by a support filament. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the bioprosthetic ligament structure as taught by Campbell for the connective tissue substitution as disclosed by Goldstein.

Claim 1, with regards to pair of bone anchors and support filament, see all Figs. of Campbell. With regards to coating of at least one matrix layer see abstract of Goldstein.

Claim 2, with regards to matrix layer colonized by cell, see col. 8, lines 40-59 of Goldstein.

Claim 3, with regards to degree of substitution, see disclosure of Campbell.

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Claim 4, with regards to type of connective tissue, see col. 3, lines 15-24 of Goldstein.

Claim 5, with regards to human, see col. 2, lines 17-41 of Goldstein.

Claim 6, with regards to non-human, see col. 4, lines 11-13 of Goldstein.

Claim 7, with regards to bone anchor, see col. 2, lines 5-16 and Figs. of Campbell.

Claim 9, with regards to matrix layer, see col. 8, lines 40-59 of Goldstein.

Claim 10, with regards to support filament, connective tissue used in both Campbell and Goldstein is composed of natural fibers and biocompatible molecules.

Claim 11, with regards to matrix layer comprising a cell, see col. 9, lines 34+ of Goldstein.

Claim 12, with regards to autologous cell, see col. 9, lines 38-39 of Goldstein.

Claim 13, with regards to heterologous cell, see col. 4, lines 11-13 of Goldstein.

Claim 14, with regards to fibroblasts, see col. 9, lines 58+ of Goldstein.

Claim 15, with regards to biologically active molecule, see col. 9, line 58- col. 10 line 52 of Goldstein.

Claim 16, with regards to lyophilized filament, see col. 4, line 61- col. 5 line 11 of Goldstein.

Claims 8, 17-24, and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein as modified by Campbell further in view of Altman et al (USPN 6,287,340).

Goldstein as modified by Campbell discloses an implant for connective tissue substitution comprising a pair of bone anchors joined at their proximal ends by a support filament that is coated by a matrix layer of sufficient thickness to allow for colonization by a cell. Goldstein as modified by Campbell discloses all of the claimed elements except for the

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particulars pertaining to the type of collagen matrix. Altman et al teaches a bioengineered cruciate ligament with a matrix material composed of collagen gel, which enhances the matrix and promotes cell adhesion. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the collagen gel as taught by Altman to enhance the matrix material of the implant disclosed by Goldstein.

Claim 8, with regards to collagen gel matrix, see col. 4, lines 50+ of Altman.

Claim 17, see claim 8, supra.

Claim 18, see claim 16, supra.

Claim 19, see claim 16, supra.

Claim 20, see claim 16, supra.

Claim 21, see claim 2 and 11, supra.

Claim 22, see claim 12, supra.

Claim 23, see claim 13, supra.

Claim 24, see claim 14, supra.

Claim 45, with regards to recombinant collagen, the applicant's specification (paragraph [0058] discloses that types of recombinant collagen are fibronectin, chichitosan, and chitin. Goldstein discloses fibronectin as an extracellular matrix protein for use in preparing the implant (8:55-60).

Claim 46, with regards to collagen consisting of types I, II, and III collagen, it is inherent that if a ligament is used as the implant tissue source that is ligament is comprised of types I and III collagen.

Claim 47, with regards to animal tissue source, see (4:11-20).

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Claim 48, with regards to animal tissue selected from tendon, skin, cornea, etc., see (3:15-24).

Response to Arguments

Applicant's amendments to the specification, oath & declaration, and drawings have been considered and the rejections of these components have been withdrawn.

Applicant's arguments filed October 26, 2003 have been fully considered but they are not persuasive. Goldstein fully discloses the method of preparing an allogeneic or xenogeneic tissue matrix comprising tissues selected from meniscus, skin, ligament, tendon and other connective tissues (3:15-24). The applicant's arguments are narrower than the claims. Goldstein as modified by Campbell teaches a ligament implant composed of the same materials suggested by the applicant and further teaches the structure of the claimed implant. The applicant's arguments fail to render independent claim 1 patentable over Goldstein in view of Campbell. As discussed above, claims 1-24 and 45-48 remain rejected under 35 U.S.C. 103(a).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

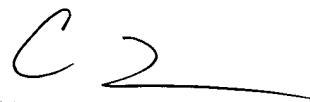
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-308-3905.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kamrin Landrem
Examiner
AU 3738

KRL


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
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